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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,452	10/23/1998	RHONA HARRIET BORTS	263/PPIR1165	8673
7590 06/02/2004 WENDEROTH LIND & PONACK 2033 K STREET N W SUITE 800 WASHINGTON, DC 20006			EXAMINER WOITACH, JOSEPH T	
			ART UNIT 1632	PAPER NUMBER

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/155,452

### Applicant(s)

BORTS ET AL.

### Examiner

Joseph T. Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 50-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 8, 2004 has been entered.

**DETAILED ACTION**

This application is a 371 National stage filing of PCT/GB97/00875, filed March 27, 1997, which claims benefit to provisional application 60/014,490, filed April 1, 1996.

Applicants amendment filed March 8, 2004, has been received and entered. Claims 1-49 have been canceled. Claims 50-63 have been added. Claims 50-63 are pending.

***Election/Restriction***

Claims 50-63 are pending. The newly submitted claims have been amended from methods and processes practiced in the species of animals to methods encompassing the non-elected species of yeast. Applicant was required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Upon the allowance of a generic claim, applicant would be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). In this case, Applicants have cancelled all the claims to the elected species, so a generic claim exists no longer exists.

Claims 50-63 are currently under examination as they are directed to the elected species of yeast.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 50, 55 and 56 are vague and unclear to whether the “genetically or physiologically” manipulation is related to providing the sequences for homologous recombination or if it is related to rendering the mismatch repair system. The metes and bounds of the claim are unclear because what and how the claimed method steps are specifically practiced can not be determined. Additionally, it is noted that upon review of the teaching of the present specification Examiner can not find guidance for physiologically disabling the mismatch repair system. Further, it is unclear how one would physiologically disable only one homologue as required in dependent claims (for example claims 52, 61 and 62). More clearly indicating the specific steps encompassed by the claims would address the basis of the rejection.

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Claim 52 is unclear in the recitation of mutS and mutL in particular in the context of the yeast system being used because these gene do not exist in yeast. mutS and mutL are names of bacterial genes, and it is unclear if the yeast comprise mutated heterologous sequences of these genes, or if the claim means to refer to PMS1 and MSH2, respectively, as the endogenous yeast sequences. Indicating the altered sequences are a “homologue” fails to clearly indicate the metes and bounds of the claim to what specific sequences are present in the yeast used in the claimed method.

Claim 57 is unclear to whether the hybrid “cells according to claim 56” must be made by practicing the steps of claim 56, or if a hybrid yeast cell can be acquired by other means wherein the cells obtained would be the same as those derived by the method of claim 56. For example, from the teachings in the specification, a yeast with a non-homologous gene sequence inserted into a gene can be generated by the claimed method, however the same yeast could be made by providing and inserting the appropriate vector sequences by methods known in the art.

Claim 63 is unclear in the recitation that the cells “are germ-line cells” because yeast are single cell organisms and what would be considered a germ cell is not clearly set forth in the specification nor in the art of record. It is unclear if any yeast would be considered a germ-line cell because it is capable of giving rise to daughter cells, thus how this claimed embodiment further limits claim 56.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Selva *et al.*

(IDS reference, March 1995).

The claimed method comprises modifying genes encoding mismatch repair enzymes in yeast and allowing for homologous recombination of sequences that comprise up to 30% base mismatches. Dependent claims set forth specific mismatch repair enzymes and that the altered sequences are comprised in a gene which can be subsequently expressed. Selva *et al.* teach that altering mutL and mutS result in an increase in homologous recombination of divergent sequences. Using the yeast system, MSH2 and PMS1 are altered and the affects on the resulting yeast are analyzed. The system used allowed for recombination that would result in a predictable outcome depending on the specific gene conversion that occurred. Selva *et al.* the use of non-homologous sequences (Figure 1) and report the affect of various alterations in recombination of the various strains (Tables 2 and 3).

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach

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